§111.16

- (f) *Plumbing*. The plumbing in your physical plant must be of an adequate size and design and be adequately installed and maintained to:
- (1) Carry sufficient amounts of water to required locations throughout the physical plant;
- (2) Properly convey sewage and liquid disposable waste from your physical plant:
- (3) Avoid being a source of contamination to components, dietary supplements, water supplies, or any contact surface, or creating an unsanitary condition:
- (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and
- (5) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary supplements, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities.
- (g) Sewage disposal. You must dispose of sewage into an adequate sewage system or through other adequate means.
- (h) Bathrooms. You must provide your employees with adequate, readily accessible bathrooms. The bathrooms must be kept clean and must not be a potential source of contamination to components, dietary supplements, or contact surfaces.
- (i) Hand-washing facilities. You must provide hand-washing facilities that are designed to ensure that an employee's hands are not a source of contamination of components, dietary supplements, or any contact surface, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.
- (j) *Trash disposal*. You must convey, store, and dispose of trash to:
- (1) Minimize the development of odors;
- (2) Minimize the potential for the trash to attract, harbor, or become a breeding place for pests;
- (3) Protect against contamination of components, dietary supplements, any contact surface, water supplies, and grounds surrounding your physical plant; and

- (4) Control hazardous waste to prevent contamination of components, dietary supplements, and contact surfaces.
- (k) Sanitation supervisors. You must assign one or more employees to supervise overall sanitation. Each of these supervisors must be qualified by education, training, or experience to develop and supervise sanitation procedures.

§ 111.16 What are the requirements under this subpart C for written procedures?

You must establish and follow written procedures for cleaning the physical plant and for pest control.

§ 111.20 What design and construction requirements apply to your physical plant?

Any physical plant you use in the manufacture, packaging, labeling, or holding of dietary supplements must:

- (a) Be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitizing operations;
- (b) Have adequate space for the orderly placement of equipment and holding of materials as is necessary for maintenance, cleaning, and sanitizing operations and to prevent contamination and mixups of components and dietary supplements during manufacturing, packaging, labeling, or holding;
- (c) Permit the use of proper precautions to reduce the potential for mixups or contamination of components, dietary supplements, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. Your physical plant must have, and you must use, separate or defined areas of adequate size or other control systems, such as computerized inventory controls or automated systems of separation, to prevent contamination and mixups of components and dietary supplements during the following operations:
- (1) Receiving, identifying, holding, and withholding from use, components, dietary supplements, packaging, and labels that will be used in or during the manufacturing, packaging, labeling, or holding of dietary supplements;
- (2) Separating, as necessary, components, dietary supplements, packaging,